REMARKS

This application, as amended, contains claims 1-5 and 7-13. Claim 6 has been cancelled. Claims 1 and 12 are independent and have been amended herein to recite the amount of sucralose (0.005 to about 10 % by weight) and that the amount of fat is on a weight basis. No new matter has been added.

Claim 1 now recites a tablet capable of being chewed or disintegrated in the oral cavity prior to swallowing, comprising a pharmaceutically active ingredient and a matrix comprising directly compressible dextrose monohydrate and about 0.005 to about 10 % by weight of sucralose. The tablet contains less than 5% by weight of fat and said matrix is substantially free of non-saccharide, water soluble polymeric binders.

Claim 12 also recites a tablet capable of being chewed or disintegrated in the oral cavity prior to swallowing, comprising a pharmaceutically active ingredient and a matrix comprising directly compressible dextrose monohydrate and about 0.005 to about 10 % by weight of sucralose. The matrix also comprises at least one disintegrating agent selected from microcrystalline cellulose, starch, sodium starch glycolate, crosslinked polyvinylpyrrolidone, crosslinked carboxymethylcellulose, and mixtures thereof; at least one lubricant selected from magnesium stearate, stearic acid, and mixtures thereof; and optionally an auxiliary ingredient selected from fillers, sweeteners, surfactants, glidants, acidulents, antioxidants, preservatives, coloring, flavoring agents, and mixtures thereof. The tablet is substantially free of triglycerides and said matrix is substantially free of non-saccharide, water soluble polymeric binders.

In the Office Action mailed August 19, 2002, the Examiner rejected Claims 1-13 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,684,534 to Valentine in view of U.S. Patent No. 4,327,076 to Puglia. The Examiner argued that Valentine teaches a chewable tablet comprising active ingredients, dextrose monohydrate and sucrose, according to the Examiner an obvious variant of sucralose. Puglia was cited for a teaching of a compressed tablet containing fats in the range of 2 to about 45%. The Examiner maintained that applicants' recitation of amounts of fat (less than 5 % by weight)and water soluble binder (substantially none) were obvious, optimum ranges.

Applicants respectfully request reconsideration of this rejection. Applicants disagree that the differences in the amounts presently claimed and the amounts taught by the

references are without patentable distinction. Contrary to the Examiner's arguments, these amounts are important to both the references and the claimed invention.

As previously explained, the Valentine tablet comprises an active ingredient and an agglomerate. The agglomerate in turn comprises a carbohydrate such as dextrose monohydrate or sucrose held together by water soluble binder. According to Valentine, "[t]he quantity of water soluble binder is somewhat critical and should be in the range of from about 1 percent to about 10 percent by weight of the agglomerate (without active ingredient)...with the carbohydrate-based particles comprising from about 90 percent to about 99 percent by weight of the agglomerate (without active ingredient)." Column 2, lines 37-45. Column 4, lines 2-7 of Valentine teaches that the agglomerate is from 50 to 90 % by weight of the combined weight of the agglomerate and the active ingredient. Accordingly, Valentine's carbohydrate comprises at least 45 % by weight of the combined weight of the agglomerate and active ingredient.

Applicants' claims now recite that the amount of sucralose in the claimed tablet is about 0.005 to about 10 % by weight. This is clearly neither taught nor suggested by the at least 45 % by weight level used by Valentine. Note Valentine's examples V and VI, the only ones employing sucrose, describe agglomerates containing 98.2 and 95 % by weight, respectively, of sucrose. These substantial differences in the amounts of sucrose and sucralose show that, as previously stated, the two are not readily interchangeable. Sucralose is 600 times sweeter than sucrose. A tablet containing 45 % by weight of sucralose would frankly be huge.

Applicants also point out that nowhere does Valentine disclose combinations of dextrose monohydrate and sucrose (or, of course, sucralose). As explained on page 2, lines 14-17 of applicants' specification, it was known that conventional high intensity sweeteners combined with dextrose monohydrate result in age related browing. It is unexpected that the claimed combination of directly compressible dextrose monohydrate and sucralose does not cause unwanted discoloration. Note applicants' claim 4, which recites a weight ratio of dextrose monohydrate to sucralose of at least about 25:1. This is also neither taught nor suggested by Valentine.

Moreover, neither Valentine nor Puglia teach or suggest applicants' recitation that the claimed tablet be substantially free of non-saccharide, water soluble polymeric binders. Valentine describes these as critical to his composition, while the present invention can

advantageously dispense with them, as the tablet of the invention is preferably made by direct compression.

For these reasons, the claimed invention is patentable over Valentine and Puglia, alone or in combination. Reconsideration of the application is therefore requested.

Respectfully submitted,

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